

AMENDMENTS TO THE CLAIMS

Claims 1-39 are cancelled.

40. (Previously Presented) Process of making crystals of 9-((1,3-DIHYDROXYPROPAN-2-YLOXY) METHYL)-2-AMINO-1HPURIN1- 6-(9H)-ONE, free from alkaline residues comprising:

- a) Suspending 9-((1,3-DIXYDROXYPROPAN-2-YLOXY)METHYL)-2-AMINO-1H-PURIN-6-(9H),ONE in demineralized water;
- b) Elevating the pH to a range between 10.5 and 12.5 by adding an inorganic base;
- c) Elevating the temperature of the resulting solution 1 (b) to a range between 75° and 90°C;
- d) Adding an inorganic or organic acid, thus adjusting the pH into a range from 4.5 to 5.5;
- e) Cooling the solution to a temperature ranging from 5° to 7°C and keeping the resulting crystals of 9-((1,3-DINYDROXYPROPAN-2-YLOXY)METHYL)-2-AMINO-1H-PURIN- 6-(9H)-ONE under stirring for 25 to 40 minutes;
- f) Filtering the resulting crystals from 1(e) and washing the crystals with an organic solvent selected from the group comprising acetone, ethanol, methanol and isopropanol;
- g) Intensely refluxing the resulting crystals from 1 (f) in an organic solvent selected from the group consisting of methanol, ethanol, propanol, isopropanol and butanol, for a period of time ranging from 3 to 4 hours;
- h) Cooling the resulting suspension from 1(g) to a temperature ranging from 20° and 30°C, filtering the crystals and drying them under vacuum and at a temperature ranging from 60° and 80°C, thus obtaining crystals of 9-((1,3-DIHYDROXYPROPAN-2-YLOXY) METHYL)-2-AMINO-1HPURIN1-6-(9H)-ONE that are free from alkaline residues.

41. (Previously Presented) The process according to claim 40, in which the inorganic base used in 1(b) is selected from the group consisting of potassium hydroxide, lithium hydroxide and sodium hydroxide.

42. (Previously Presented) The process according to claim 41, in which the inorganic base is sodium hydroxide.

43.(Previously Presented) The process according to claim 40, in which the organic solvent used in steps 1(f) and 1(g) is isopropanol.

44.(Currently Amended) A ready-for-use sterile, stable, pharmaceutical formulation, in a closed system, comprising an injectable aqueous solution of crystals from active principle 9-((1,3-DIHYDROXYPROPAN-2-YLOXY)METHYL)-2-AMINO-1H-PURIN-6-(9H)-ONE as its free acid form, produced by the process of claim ~~40~~40, diluted in glucose 5% solution or sodium chloride 0.9% solution, with pH ranging from 3.0 to 6.9, and being packed in a flexible bag manufactured with a tri-laminated material composed by three distinct layers, being an external layer of polyester, an intermediate layer of polyethylene and the inner layer of propylene copolymer.

45.(Previously Presented) The pharmaceutical formulation according to claim 44, in which the solution is a sodium chloride 0.9% solution, and the pH is within the range of 4.5 to 6.9.

46.(Previously Presented) The pharmaceutical formulation according to claim 44, in which the solution is a glucose 5% solution, and the pH is within the range of 3.2 to 6.5.